

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-12 are pending in the application, with 1 being the independent claims. Claims 1, 2, and 8-11 are sought to be amended without prejudice to or disclaimer of any subject matter cancelled therein. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Objections to the Drawings

The objections stipulated in Form PTO 948, dated March 4, 2002, have been noted. Pursuant to 37 C.F.R. § 1.111(b), Applicants respectfully request that these objections be held in abeyance until allowable subject matter is indicated since a reply to the objections is not necessary for further consideration of the claims.

Rejections under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 1-12 as being indefinite under 35 U.S.C. § 112, second paragraph. Applicants believe the Examiner's rejections are no longer valid and/or have been rendered moot by the proposed amendments. As such, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections of claims 1-12, and allowance thereof.

Rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1, 8 and 10 under 35 U.S.C. § 102(b), as being anticipated by one or more of the following documents:

(1) Aultman, K. S., *et al.*, "Partial P₁ Nuclease Digestion as a Probe of tRNA Structure," Eur. J. Biochem. pp 471-476, (Dept. of Biochem., Louisiana State University, 1982) (herein referred to as "Aultman"); and

(2) Kandzia, R., *et al.*, "Purification and Characterization of Lanatoside 15'-O-acetylerase from *Digitalis lanate* Ehrh.," Planta, pp 383-389 (Springer-Verlat, 1998) (herein referred to as "Kandzia").

Alternatively, the Examiner rejected claims 1, 8 and 10 under 35 U.S.C. § 103, as being obvious in view of Aultman or Kandzia. Each document is discussed separately below.

a. Aultman Rejections

In the Office Action, the Examiner rejected claims 1 and 10 under 35 U.S.C. § 102(b) as being anticipated by Aultman, and alternatively under 35 U.S.C. § 103 as being obvious in view of Aultman.

The claims have been amended to more particularly and distinctly recite features not taught or suggested by Aultman. Moreover, notwithstanding the proposed amendments, Aultman does not teach each and every element or limitation of Applicants' invention. Specifically, Aultman teaches a method for partial nuclease digestion of tRNA. Fragments produced by the partial nuclease digestion are identified by polyacrylamide gel electrophoresis, and are visualized by autoradiography. Films, presumptively of the autoradiogram, are scanned with a Helena Quick Scan densitometer. An average percentage of the total readable band intensity is expressed for groups of fragments. Graphical representations of the readable band intensity are charted in Figs. 4 and 5.

Regarding claim 1, the "scanned" images in Aultman are not digitized to measure intensity values of "each" fragment. This is an important feature because the intensity values (e.g., the chromatographic data gathered from the digital images) of "each" fragment are used to derive a "model" of fragment population information, as recited in

claim 1. Therefore, Aultman cannot disclose the analysis of a model of fragment population information that objectively and quantitatively determines catalytic results, such as the unit activity of an enzyme. The graphical representations, shown in Aultman, merely disclose the presence of particular fragment groups. These graphical representations are not analyzed to determine a catalytic result.

As such, Applicants respectfully submit that Aultman does not teach or suggest Applicants' claimed invention, as recited in claim 1. Claim 10 depends from claim 1 and, therefore, is patentable over Aultman for at least the reasons stated above. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of the aforesaid claims, and allowance thereof.

b. Kandzia Rejections

In the Office Action, the Examiner rejected claims 1 and 8 under 35 U.S.C. § 102(b) as being anticipated by Kandzia, and alternatively under 35 U.S.C. § 103 as being obvious in view of Kandzia.

The claims have been amended to more particularly and distinctly recite features not taught or suggested by Kandzia. Moreover, notwithstanding the proposed amendments, Kandzia does not teach each and every element or limitation of Applicants' invention. Specifically, Kandzia describes a procedure for purifying a Lanatoside 15'-O-acetylcysteine (LAE) protein. Sodium dodecyl sulfate-polyacrylamide gel electrophoresis is performed on the purified LAE protein, and Fast Blue B is added for staining after

electrophoresis. The intensity of the 39 kDA band corresponding to the LAE activity is profiled, and a HPLC chromatogram of the proteolytic fragments is displayed.

Regarding claim 1, the images and chromatogram in Kandzia (shown in Fig. 3-4) are not digitized to measure intensity values of "each" fragment. As discussed above, this is an important feature because the intensity values (e.g., the chromatographic data gathered from the digital images) of "each" fragment are used to derive a "model" of fragment population information, as recited in claim 1. Therefore, Kandzia cannot disclose the analysis of a model of fragment population information that objectively and quantitatively determines catalytic results, such as the unit activity of an enzyme. The chromatogram and other graphical representations, shown in Kandzia, merely disclose the presence of particular fragments. These graphical representations are not analyzed to determine a catalytic result.

As such, Applicants respectfully submit that Kandzia does not teach or suggest Applicants' claimed invention, as recited in claim 1. Claim 8 depends from claim 1 and, therefore, is patentable over Kandzia for at least the reasons stated above. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of the aforesaid claims, and allowance thereof.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

A markup version of claims 1, 2, and 8-11 are provided below:

1. (Once Amended) A method for measuring catalytic activity of a test aliquot, comprising the steps of:

distributing the test aliquot into a separation medium, wherein the test aliquot includes one or more macromolecular fragments resulting from the catalytic activity;

[processing the test aliquot to produce] enabling said one or more fragments to separate within [in the] said separation medium;

[capturing] digitizing an image of [the] said one or more fragments to measure intensity values [from] for each fragment from said image;

processing said intensity values to derive a fragment population model of said one or more fragments; and

analyzing said [intensity values] fragment population model to determine a catalytic result.

2. (Once Amended) A method according to claim 1, wherein said distributing step comprises the step of:

distributing the test aliquot among a plurality of reaction wells within the separation medium, wherein said [analyzing] processing step

comprises placing said intensity values into intensity profiles, each intensity profile representing one or more fragments from a corresponding reaction well.

8. (Once Amended) A method according to claim 1, further comprising the step of:

staining the test aliquot with a reporter molecule prior to said [capturing] digitizing an image step.

9. (Once Amended) A method according to claim 8, wherein the test aliquot is not de-stained prior to said [capturing] digitizing an image step.

10. (Once Amended) A method according to claim 1, wherein said [processing] enabling step comprises the step of:

performing electrophoretic separation to resolve at least one of DNA fragments and RNA fragments.

11. (Once Amended) A method according to claim 1, wherein said distributing step comprises the step of:

transferring a diluted enzyme concentration to one or more reaction [wells within the separation medium] chambers to digest [to produce the test aliquot, wherein said one or reaction wells contain] a DNA substrate

disposed in each reaction chamber, wherein said one or more macromolecular
fragments result from the digestion of said DNA substrate.